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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,035	05/22/2001	Stanislaw R. Burzynski	10379.0047.DVUS00	1265

7590

04/24/2003

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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/863,035

Applicant(s)

BURZYNSKI, STANISLAW R.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10,15,16,28-30,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10,15,16,28-30,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

nt(s)

ce of References Cited (PTO-892)

ce of Draftsperson's Patent Drawing Review (PTO-948)

ation Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Burzynski patent.

The Burzynski patent has an effective date of September 14, 1993 while the instant application has an effective date of July 23, 1998. The Burzynski patent discloses the combination of formula IV and I as "antineoplaston AS2-1 (1:4 ratio of sodium salt of phenylacetylglutamine and sodium salt of phenylacetic acid) is particularly preferred... 100mg /ml intravenous infusions» (col. 4, line 68 to col. 5, line 5). The patent teaches "distilled sterile water" as a carrier (col. 6, line 62) and a "concentration in the suspension medium can vary from 0.1 to 100mg active ingredients/ml."

The patent in col. 3, line 55 to col. 4, line 28 discloses the pharmaceutical composition of combination of A and B, which are the compounds in formula I and IV of the instant claims. The prior art patent does not disclose a specific composition of formula I and IV in water.

Accordingly, the skilled in this art would find ample motivation from the prior art supra to employ water as a carrier since the prior art teaches the application of water as a carrier.

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Claims 28-30, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Burzynski patent. The Burzynski patent has an effective date of September 14, 1993 while the instant application has an effective date of July 23, 1998. The Burzynski patent discloses a patient "diagnosed with Hodgkin's disease " (col.7, lines 52-53) being treated with "antineoplaston AS 2-1, 100mg/ml infusions ..." at a "dosage of this formulation was gradually increased to 20g/24h " (col.8, lines 1-4), or 29g/kg/day.

" A complete evaluation preformed on Jun. 22, 1990 revealed marked improvement in the patient's condition. The patient was feeling very well and did not have complaints. The lines and spleen were no longer enlarged by physical examination " (col.8, lines 6-9). The term "antineoplaston AS2-1 is defined on col.4, last 1 to col.5, lines 2, 4 and 5 as a " 1:4 ratio of sodium salt of phenylacetyl-glutamine and sodium salt of phemylacetic acid..." at " 100mg/ml intravenous infusions". The instant claim 28 is directed to treating a neoplastic disease broadly employing formula 1 to formula IV in a 1:4 ratio employing 70mg/ml to 150mg/ml of the active ingredients. Claim 47 defined the neoplastic disease as "Hodgkin's disease " (claim 47, line 11). The prior art patent fails to set forth the rate in ml. Per hour. Accordingly, one skilled in this art would find ample motivation from the prior art supra to employ the prior art combination to treat neoplastic diseases with a reasonable expectation that said combination would be effective to combat said neoplastic diseases including Hodgkin's disease.

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Claims 28-30 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific neoplastic disease or tumor disclosed, does not reasonably provide enablement for the term "neoplastic disease" or "...tumor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms "neoplastic disease" in claim 28-30 and "tumor" in claim 46 lack clear exemplary support in the specification as filed.

The Carter et al. reference is cited to show that no known anticancer drug is effective against all types of cancers.

The cancer therapy art remains highly unpredictable and no examples exist for efficacy of a combination of drugs against neoplastic diseases or tumors generally.

Therefore, based on the unpredictable nature of the invention and state of the prior art, lack of guidance and working examples, and extreme breadth of the claims, one skilled in this art could not use the entire scope of the claimed invention without undue experimentation. Changing the term "neoplastic disease" or "tumor" to the specific tumors or neoplastic disease disclosed would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd
April 18, 2003



JEROME D. GOLDBERG
PRIMARY EXAMINER